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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/839,186

04/19/2001

Matthew L. Meyerson

7032/2002

1540

29933

7590

01/14/2004

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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,186

Applicant(s)

MEYERSON, MATTHEW L.

Examiner

Marianne P. Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 29-31, 50, 51, 53-58 and 60-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 29-31, 50-51, 53-58, 60-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 61-64 have been newly introduced.

Claims 1-26, 29-31, 50-51, 53-58, 60-64 are under consideration by the examiner.

Applicant's arguments filed 7/14/03 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-26, 29-31, 50-51, 53-58, and 60-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Independent claims 1, 2, 3, and 50 have been amended to be directed to methods of using a computer system to determine the presence of a microbe inhabiting a host organism. The final step in each claim recites "wherein absence...indicates that said at least one sequence is a candidate sequence belonging to a microbe, thereby indicating the presence of a microbe inhabiting said host organism." The method steps as recited still do not provide the information required by the goal of the preamble. The methods as written do not evaluate the candidate sequence to determine if in fact they correspond to a microbial sequence. The steps as written are more properly a method of identifying candidate microbial sequences. Presently, the steps only indicate that at least one sequence is not present in the database of the host organism genomic sequences.

Likewise, the method steps of claim 58 do not determine the presence of a microbe inhabiting host organism as required by the preamble. The steps only identify the presence of an expressed sequence in common with at least one non-microbial host organism. This would include, for example, repeat elements.

The only claim that comes close to addressing this problem is claim 23. However, the step set forth here requires no result (e.g. use candidate sequence as query sequence and determine if candidate sequence is present or absent) and even if it did, would generate a result which is not used in the step determining presence or absence of the independent methods (e.g. absence of the candidate sequence in the microbial database means the candidate sequence is not microbial).

As set forth in the prior Office action the claims have no limitations as to how presence or absence of a sequence is determined. Applicant has argued that the claim recitations of presence or absence are limited by the specification's matching definition. Applicant points to page 8 and relies upon the definitions of "match," "present," and "absent." The specification recites that a match between sequences is considered to be "a level of sequence similarity equivalent to a BLAST score ranging from 40 (equivalent of 20 consecutive identical nucleotides) to 2000 (the equivalent of 1000 consecutive identical nucleotides)." This does not limit the claims to a match of 20 consecutive or 1000 consecutive identical nucleotides for determining presence or absence. It cannot be determined from the specification what degree of similarity with different runs of consecutive identical nucleotides would give a BLAST score ranging from 40-2000 nor what particular version of BLAST nor the parameters/penalties applicant intends for determining such scores.

As set forth in the prior Office action, the specification does not provide databases containing expressed sequence tags (ESTs) or genomic sequences for all host organisms embraced by the claims. While the specification indicates that many such databases are available, there is no evidence that these databases possess the type of sequence integrity (produced from host organisms not having a particular pathogenic condition, see for example claim 8) required by the claims. Applicant argues that databases containing contaminating microbial sequences can be used successfully in the methods and proffers the Meyerson declaration in support thereof. This is not persuasive. The claims require databases containing or excluding particular types of sequence data. To enable the claimed methods, these databases must be enabled. Applicant is arguing that a different method using a different type of database is enabled. Applicant's response is viewed as an admission that databases such as those set forth in claims 2, 3, 8, for example, would not have been available at the time of the invention.

Claims 4-6, 21-24, 29-31, and 53-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-6 recite limitations with respect to the type of candidate sequence found. These claims remain confusing. These appear to be circular claims requiring knowing what one would find BEFORE the method is executed. These claims are not viewed as setting forth positive, active steps that must be performed in addition to the method of claims 1, 2, or 3 (e.g. determining whether the candidate sequence belongs to a symbiotic microbial organism by performing steps a, b, and c).

Claim 21 recites that the candidate sequence is identified through subtractive hybridization. This is confusing as claims 3 and 10 identify the candidate sequence by computationally searching databases.

Claims 23-24 are confusing because the added step doesn't make clear if or how the results of any query are used in determining the presence of a microbe inhabiting a host organism.

Claim 53 is confusing in depending upon cancelled claim 52.

Claim Rejections - 35 USC § 102

Claims 1, 3-6, 50-51, 53, and 58-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Sabatini et al. (U.S. Patent No. 5,966,712).

This rejection is maintained for reasons of record. Sabatini et al. determines presence or absence of sequences thereby identifying candidate sequences as required by the claims. One of ordinary skill in the art would have reasonably concluded if the host sequence searched wasn't found in the host organism sequence database, it was a candidate sequence as belonging to another organism, including microbes. The limitation "thereby indicating the presence of a microbe inhabiting said host organism" does not add a positive, active step that is not met by the prior art.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

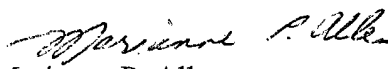
Art Unit: 1631

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa